Clinical Policy: Pirfenidone (Esbriet)

Reference Number: ERX.SPA.173
Effective Date: 01.11.17
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Pirfenidone (Esbriet®) is a pyridone.

FDA Approved Indication(s)
Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Esbriet is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Diagnosis of IPF;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Member meets (a and b):
   a. Pulmonary fibrosis on high resolution computed tomography (HRCT) with one of the following (i or ii):
      i. Usual interstitial pneumonia (UIP) pattern;
      ii. Probable or indeterminate UIP pattern, and surgical lung biopsy or cellular analysis of bronchoalveolar lavage fluid confirms the diagnosis of IPF;
   b. Known causes of pulmonary fibrosis have been ruled out *(see Appendix D);*
5. Baseline forced vital capacity (FVC) ≥ 50% of predicted;
6. Baseline carbon monoxide diffusing capacity (DLCO) ≥ 30% of predicted;
7. Esbriet is not prescribed concurrently with Ofev®;
8. Member is not an active smoker as evidenced by recent (within the last 30 days) negative nicotine metabolite (i.e., cotinine) test;
9. Dose does not exceed:
   a. Days 1 through 7: 801 mg (3 capsules or 1 tablet) per day;
   b. Days 8 through 14: 1,602 mg (6 capsules or 2 tablets) per day;
   c. Days 15 and onward: 2,403 mg (9 capsules or 3 tablets) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. Esbriet is not prescribed concurrently with Ofev;
4. If request is for a dose increase, new dose does not exceed 2,403 mg (9 capsules or 3 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

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IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DLCO: carbon monoxide diffusing capacity
FDA: Food and Drug Administration
FVC: FVC: forced vital capacity
HRCT: high resolution computed tomography
IPF: idiopathic pulmonary fibrosis
UIP: usual interstitial pneumonia

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: American Thoracic Society (ATS) 2018 IPF Guidelines

- ATS diagnostic criteria for IPF are built around pulmonary fibrosis findings on HRCT and exclusion of known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity).
- UIP is the hallmark radiologic pattern of IPF. Honeycombing is a distinguishing feature of UIP and must be present for a definite HRCT diagnosis of UIP to be made.
- In patients with a probable or indeterminate UIP pattern, surgical lung biopsy or cellular analysis of bronchoalveolar lavage fluid is recommended to confirm the diagnosis of IPF.

Appendix E: General Information

- Smoking causes decreased exposure to Esbriet, which may alter the efficacy profile of Esbriet. Instruct patients to stop smoking prior to treatment with Esbriet and to avoid smoking when using Esbriet.
- The Esbriet pivotal studies included only patients with mild to moderate lung impairment per FVC and DLCO.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IPF	Days 1 - 7: 267 mg PO TID Days 8 - 14: 534 mg PO TID Days 15 onward: 801 mg PO TID	Days 1 - 7: 801 mg/day Days 8 - 14: 1,602 mg/day Days 15 onward: 2,403 mg/day

VI. Product Availability

- Capsule: 267 mg
- Tablets: 267 mg, 801 mg

VII. References

1. Esbriet Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; July 2019. Available at: www.esbriet.com. Accessed June 30, 2021.
2. Raghu G, Rochwerg B, Yuang Z, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis, an update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015; 192(2): e3-e19.
3. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J Respir Crit Care Med. 2011; 183: 788-824.
4. Raghu G, Remy-Jardin M, Myers JL, et al. An official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Diagnosis of Idiopathic Pulmonary Fibrosis. Am J Respir Crit Care Med. 2018 September; 198(5): e44-68.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q17 Annual Review Converted to new template. Added age restriction as safety and efficacy have not been established in pediatric patients per PI. Added dosing information related to initial titration period.	09.27.17	11.17
3Q 2018 annual review: removed requirement for high-resolution computed tomography or surgical lung biopsy findings confirming diagnosis; references reviewed and updated.	05.10.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: for IPF added HRCT and rule-out criteria to align with previously P&T-approved approach for IPF for Ofev; references reviewed and updated.	06.22.20	08.20
3Q 2021 annual review: added requirements for HRCT UIP pattern and surgical biopsy/bronchoalveolar lavage per ATS guidelines; added baseline FVC/DLCO requirements per pivotal trial inclusion criteria; added requirement against concurrent use with Ofev; added requirement that member is not an active smoker; references reviewed and updated.	06.30.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.